

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.*
JAMES F. ALLEN,

Plaintiff,

v.

ALERE HOME MONITORING, INC.;
ROCHE HEALTH SOLUTIONS, INC.;
ADVANCED CARDIO SERVICES;
CARDIOLINK CORP.; MDINR, LLC;
PATIENT HOME MONITORING, INC.;
TAMBRA INVESTMENTS, INC. d/b/a
REAL TIME DIAGNOSTICS; and US
HEALTHCARE SUPPLY, LLC,

Defendants.

Civil Action No. 16-cv-11372-PBS

**PLAINTIFF-RELATOR'S RESPONSE TO DEFENDANT ALERE HOME
MONITORING, INC.'S NOTICE OF COMPLIANCE WITH ORDER
TO PRODUCE RECORDS**

Plaintiff-Relator James F. Allen ("Allen") hereby provides the following response to the notice of compliance with order to produce records (*Docket No. 148*) filed by defendant Alere Home Monitoring, Inc. ("Alere").

Alere uses its notice of compliance to provide the Court with yet another excuse for its clear submission of charges for services that were not performed. This is Alere's third explanation, and none are valid. First, Alere claimed that it had actually submitted fewer claims for reimbursement than it was entitled to make. *Docket No. 96, pp. 16-17*. Alere then suggested that it may have submitted charges for "unbilled tests performed earlier." *Docket No. 132, p. 9*. Now Alere represents that the bills were submitted pursuant to a corporate policy of charging Medicare even when INR tests are not completed. *Docket No. 148*. Alere's current explanation amounts to

an admission that it routinely submitted false claims. Moreover, Alere's changing factual representations illustrate that this cannot be a matter appropriate for a motion to dismiss.

In addition to being inconsistent, Alere's explanations contradict the allegations of the Amended Complaint, which must be taken as true, and which make no reference to any type of test error. The Amended Complaint alleges that Alere submitted claims for reimbursement using HCPCS Code G0249 "falsely represent[ing] that it had provided Allen with supplies to perform four (4) INR tests, that Allen had in fact performed four (4) INR tests, and that Alere had reported four (4) INR tests results to Allen's physician." *Amended Complaint*, ¶¶ 254-262. Alere's contention that there were "blood sample errors" is an inappropriate factual argument. The documents produced by Alere do nothing to contradict the allegations of the Amended Complaint. As illustrated by an excerpt of the documents produced by Alere, attached hereto at Exhibit A, Alere merely prepared a spreadsheet purporting to document that a testing error occurred. There is no indication that four (4) INR tests were actually performed or that four (4) results were reported to Allen's physician. Nor is there any indication that Alere disclosed to Medicare that it was submitting charges for attempted tests that did not produce results.

Alere's current explanation also makes clear that, as alleged by the Amended Complaint, Alere's practice of billing for services not actually performed was not limited to Allen but rather was applied to all patients in its home INR testing program. Further, even if it were assumed that in some cases blood sample errors (or other problems with the supplies provided by Alere) did occur, Alere's claims for reimbursement for such attempted tests would still be false. 42 C.F.R. § 410.32(a), explicitly incorporated by Medicare's National Coverage Determination for Home Prothrombin Time INR Monitoring for Anticoagulation Management ("NCD 190.11"), requires that a physician "use[] the results in the management of the beneficiary's specific medical

problem” (emphasis added). An inconclusive test does not produce results and cannot be used for the only purpose INR testing is ordered – to evaluate the anticoagulating impact of warfarin. As illustrated by Exhibit A, Alere’s practice of counting inconclusive attempts for the purposes of HCPCS Code G0249 also violates the express terms of NCD 190.11 and CMS’s billing instructions. NCD 190.11 directs that “[s]elf-testing with the device should not occur more frequently than once a week.” Medicare’s Claims Processing Manual requires that only INR tests “not occurring more frequently than once a week” may be counted toward the four (4) tests required to submit a charge for a unit of HCPCS Code G0249. CMS Manual Chapter 32, Section 60.4.2. On both occasions that Alere inappropriately claims Allen reported a blood sample error, Alere also reported and counted a completed INR test on the same date in violation of the requirements of NCD 190.11 and the CMS Manual. *See highlighted rows of Exhibit A.* Indeed, Alere’s own instructions to patients reflect that multiple test strips can be used to obtain a single result, as patients are directed to report the number of strips associated with each individual test.¹

At worst, Alere’s has made misrepresentations to the Court in an attempt to excuse its fraudulent billing. At best, Alere has intentionally instituted a policy that violates Medicare’s regulations and billing instructions. In either case, Alere’s position requires facts to be assumed in its favor and allegations of the Amended Complaint to be ignored. Thus, Alere’s defense is inappropriate for a motion to dismiss and its motion must be denied.

[SIGNATURE PAGE FOLLOWS]

¹ Alere’s reporting options for number of test strips used range from one (1) to “5+.” Alere’s practice of counting inconclusive attempts could result in submission of charges using HCPCS Code G0249 without any actual completed tests.

Respectfully Submitted,

SMITH & BRINK, P.C.

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Dated: May 29, 2018

CERTIFICATE OF SERVICE

I, Andrew H. DeNinno, attorney for Plaintiff-Relator James F. Allen, hereby certify that I served a copy of the foregoing pleading on this date via ECF to all counsel of record identified on the Notice of Electronic Filing.